MAR 16 [illegible]

K060110

510(k) Summary

Date prepared: January 12, 2006

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92 (c).

Submitter's name, address, contact

The submitter of this premarket notification is Immunicon Corporation, 3401 Masons Mill Road, Suite 100, Huntingdon Valley, PA 19006. The official correspondent is Peter J Scott, Vice President of Quality Assurance and Regulatory Affairs (215-346-8251, fax 215-830-0751).

Identification of the Device and Predicate

The subject of this summary of Safety and Effectiveness is the Immunicon CellTracks® Analyzer II. The predicate device is the Immunicon CellTracks Analyzer II K050145. The subject device, CellTracks Analyzer II, is intended for use in traditional Clinical laboratories and Research Institutions. The common and classification name for this instrument is an Immunomagnetic Circulating Cancer Cell Selection and Enumeration System.

Intended Use

The Immunicon CellTracks Analyzer II is a semi-automated fluorescence microscope used to enumerate fluorescently labeled cells that are immuno-magnetically selected and aligned. The system is for *in vitro* diagnostic use when used in tandem with specimen preparation equipment and reagents that are legally marketed for *in vitro* diagnostic use with this device.

Device description

The CellTracks® Analyzer II is a semi-automated fluorescence microscope. The product consists of the CellTracks® Analyzer II, a dedicated computer loaded with CellTracks® software, monitor, keyboard and mouse.

The CellTracks Analyzer II is for analysis of rare cells that are isolated from biological fluids including whole blood. It is used in conjunction with the CellTracks® AutoPrep System, which automates, standardizes and optimizes the sample preparation with specific reagent kits.

The CellTracks Analyzer II is used in conjunction with the CellTracks AutoPrep System and *in vitro* diagnostic reagent kits that contain a ferrofluid-based capture reagent and immunofluorescent reagents for the detection and characterization of the captured cells. The ferrofluid reagent consists of nano-particles with a magnetic core surrounded by a polymeric layer coated with antibodies targeting the cells of interest. After Immunomagnetic capture and enrichment, fluorescent reagents are added for identification and enumeration of the target cells.

The processed reagent/sample mixture is dispensed by the CellTracks AutoPrep System into a cartridge that is inserted into a MagNest® cell presentation device. The strong magnetic field of the MagNest causes the magnetically-labeled target cells to move to the surface of the cartridge. The CellTracks Analyzer II scans the entire surface of the cartridge with a series of fluorescence filters that are defined for the assay. Cell images from the filter are compiled and presented in a gallery format for final cell classification by the user.

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Technical Characteristics Summary

The changes to the CellTracks Analyzer II software architecture reside in the operating system (OS). The current CellTracks Analyzer II utilizing MS Windows XP has been changed to Mandrake Linux. The Operating system performs basic tasks, such as recognizing input from the keyboard, sending output to the display screen, keeping track of files and directories on the disk, and controlling peripheral devices such as disk drives and printers.

This new operating system (Linux) is not compatible with the current Graphical User Interface (GUI). Therefore, we have developed a new Graphical User Interface (GUI). The Graphical User Interface is a program interface that uses a computer's graphics capabilities to make the program easier to use. Graphical interfaces use a pointing device to select objects, including icons, menus, text boxes, etc. A GUI includes standard formats for representing text and graphics. This allows users to compile defined data in a manner more usable to the operator. It does not allow them to alter the basic cell definition, count or image quality.

What has not changed with the OS replacement are: All the algorithms associated with image acquisition, analysis, cell selection, review, reporting and archiving; the logic and interface to the PC remain the same.

These modifications of the CellTracks Analyzer II do not raise any new issues of safety or effectiveness. The intended use of the device is the same.

Discussion of testing

The software testing methodology for validating CellTracks Analyzer II (Linux) was developed and executed using GAMP 4 Guide for Validation of Automated Systems approach. Test scripts were developed using the software requirements specification (SRS) and the design documents (software and database) to ensure that the software addresses all system requirements and the design elements have satisfied the software requirements. In addition to testing against the requirement and design documents, fault testing was performed on the instrument to ensure the software responds to power interruptions in different areas of the hardware. A Trace Matrix was developed to trace requirements thru design and testing.

Conclusion

The conclusion drawn from these studies is that the CellTracks Analyzer II is as safe and effective as the predicate device. No new issues of safety or effectiveness have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Immunicon Corp.
c/o Mr. Peter Scott
Vice President of Quality assurance and Regulatory Affairs
3401 Masons Mill Rd, Ste 100
Huntington Valley, PA 19006-3574

Re: k060110
Trade/Device Name: Immunicon CellTracks® Analyzer II
Regulation Number: 21 CFR 866.6020
Regulation Name: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System
Regulatory Class: Class II
Product Code: NQI
Dated: January 13, 2006
Received: January 18, 2006

Dear Mr. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060110

Device Name: Immunicon CellTracks® Analyzer II

Indications For Use: The Immunicon CellTracks Analyzer II is a semi-automated fluorescence microscope used to enumerate fluorescently labeled cells that are immuno-magnetically selected and aligned. The system is for in-vitro diagnostic use when used in tandem with specimen preparation equipment and reagents that are legally marketed for in vitro diagnostic use with this device.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Maria Chan
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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